Judge McMahon

07 CV 5586

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ROSE MOYE

Plaintiff,

-against-

MERCK & CO., INC.,

Defendant.

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CASE NUMBER:

COMPLAINT AND JURY DEMAND

JUN 12 2007

Plaintiff, by her attorneys, **DOUGLAS & LONDON, P.C.**, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION

1. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiff is a citizen of a State which is different from the State where Defendant is incorporated and has its principal places of business. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00) as to each Plaintiff.

PARTY PLAINTIFFS

2. Plaintiff, ROSE MOYE, was born on August 7, 1937, and is at all times relevant herein a resident of the State of New York.

PARTY DEFENDANT

3. Merck & Co., Inc., is incorporated under the laws of the State of New Jersey with its principal place of business in New Jersey.

4. Defendant, Merck & Co., Inc., was and still is a domestic corporation that is doing business in the State of New York.

5. Defendant, Merck & Co., Inc., transacts and conducts business in

the State of New York.

6. Defendant, Merck & Co., Inc., regularly does and/or solicits business within the State of New York.

7. Defendant, Merck & Co., Inc., derives substantial revenue from goods used or consumed in the State of New York.

8. Defendant, Merck & Co., Inc., expected or should have expected its acts to have consequences within the State of New York, and derives substantial revenue from interstate commerce within the United States of America, and New York State, more particularly.

9. At all times relevant hereto, Defendant, Merck & Co., Inc., was engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and marketing, either directly or indirectly through third parties and/or related entities, the pharmaceutical drug, Vioxx, throughout the United States.

FACTUAL BACKGROUND

10. At all relevant times, Defendant was in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell, and/or distribute the drug Vioxx.

11. Vioxx is the brand name of rofecoxib, one of a class of drugs called "prostaglandins," which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions,

arthritis and muscle pain. Prostaglandins are COX (cyclooxygenase) inhibitors; COX enzymes metabolize arachidonic acid to produce prostaglandins.

12. Vioxx is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

13. Defendant Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration (hereinafter referred to as "the FDA") on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

14. Defendant Merck also submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for oral suspension, at doses of 12.5 mg/mL, and 25 mg/mL, for relief of signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

15. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter referred to as the "NDA") for rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrheal. At the time the drug was approved by the FDA the labeling for refecoxib stated, in the section entitled "Special Studies – Upper Endoscopy in Patients with Osteoarthritis," "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers

than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastoduodenal ulcers when comparing VIOXX to placebo."

16. The "Warnings" section of the labeling for rofecoxib, at the time the drug was approved by the FDA,. contains a section, "Gastrointestinal (GI) Effects – Risk of GI Ulceration, Bleeding, and Perforation."

17. Defendant Merck submitted sNDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the sNDA, Defendant Merck performed the Vioxx GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed on January 6, 1999 through March 17, 2000.

18. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking naproxen 1000 mg/day," and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

19. In industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in statistically significant increase in hypertension and stroke. Not only did Merck do nothing to further accurately publish these studies, or warn consumers, but it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association,

Pharmacy Today, *Spin War Aside, Lessons Emerge from COX-2 Trials,* August 2000, page 3.

20. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced Merck's financial stability to the detriment of its consumers. As a result of Merck's scheme, it reaped more than $2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market.

21. Merck continued to profit from its scheme by withholding information from Plaintiffs, the consuming public, and the healthcare industry. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine in which it knowingly downplayed and/or withheld the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.

22. On or about August 29, 2001, the Journal of the American Medical Association (JAMA) published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukhisjee, et. al., showing that Merck had concealed that the relative risk of developing a "confirmed adjudicated thrombotic cardiovascular event" (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Merck's trials, including VIGOR, at a 95% confidence interval ranged from 2.2 for event –free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious

cardiovascular events among aspirin-indicated patients. *See* Mukhisjee, D., et. al., *Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors,* J.A.M.A. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users.

23. In the JAMA study, the authors stated that "by decreasing PG12 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PG12, potentially leading to an increase in thrombotic cardiovascular events." *Id.* At 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard Bing conducted scientific testing and confirmed that the Cox-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lonicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?,* J.A.C.C., 39:3, Feb. 6, 2002. This is further supported by studies completed at the Pennsylvania. Cheng, Y., et al, *Role of Prostacyclin in the Cardiovascular Response to Thromboxane A2,* Journal of Science, V. 296:539-541, Apr. 19, 2002.

24. On September 17, 2001, Thomas W. Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to Raymond V. Gilmartin, President and CEO of Defendant Merck, relating to "promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets."

25. The Warning Letter stated that Defendant Merck had "engaged in a

promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

> Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (Mis) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

26. The eight (8) page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following "**Conclusions and Requested Actions**:"

> The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.
>
> Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.
>
> This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

> Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
>
> Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.
>
> A written statement of your intent to comply with "1" and "2" above.

27. On April 11, 2002, the FDA approved a supplemental application for the use of Vioxx (rofecoxib) for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

28. The revised labeling further states that the administration of Vioxx 50 mg, was associated with a higher incidence of gastrointestinal symptoms,

> ***Clinical Studies in OA and BA, with VIOXX 50 mg (Twice the highest dose recommended for chromic use)*** In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as VIOXX 50 mg, VIOXX 50 mg OD was associated with a higher incidence of gastrointestinal symptoms (abdominal pain, epigatric pain, heartburn, nausea and vomiting), lower extremity edema, hypertension, serious adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 mg. see DOSAGE AND ADMINISTRATION.

29. Further, the "Dear Doctor" letter, approved in conjunction with the revisions to the Vioxx labeling, outlines the changes to the Vioxx labeling.

30. The revised "Patient Information" sheet does not add any information about the results of the VIGOR study.

31. The "Patient Information" sheet is the only written document that is provided to a patient for whom Vioxx is prescribed.

32. Both the initial labeling and the revised labeling are ineffective because they do not properly advise physicians and patients of the potential gastrointestinal side effects of Vioxx.

33. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that Vioxx may cause serious gastrointestinal side effects, Defendant Merck has concealed and/or downplayed the dangers associated with Vioxx, and continues to market the drug in the United States and abroad. In its 2001 Annual Report, for example, Defendant Merck states:

> The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx...The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

34. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, Defendant fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "our five key products, **VIOXX**, ZOCOR, COZAAR/HYZARR, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful plateform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter. "Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. **VIOXX**, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **VIOXX** has become the world's fastest growing branded prescription arthritis medicine, and

> it is already Merck's second largest-selling medicine. In the United States, **VIOXX** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **VIOXX** achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter. A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal complications by half compared to the NSAID naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **VIOXX** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

35. Plaintiff ROSE MOYE was a user of the drug Vioxx.

36. Upon information and belief, Plaintiff ROSE MOYE ingested and used the drug Vioxx from approximately October 2003, up through approximately July 2004.

37. Plaintiff, ROSE MOYE, suffered severe and permanent personal injuries as a result of her use of and exposure to the drug Vioxx, including suffering a myocardial infarction in or about July 2004.

FIRST CAUSE OF ACTION
(Strict Products Liability)

38. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

39. At all times herein mentioned, the Defendant, its agents, and/or servants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, sold, purchased, prescribed, and/or administered the

aforesaid Vioxx as hereinabove described and prior to the time that Plaintiff used said product.

40. The said drug product, more particularly known as Vioxx, was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

41. At those times, the said drug product Vioxx, was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, the general public and, in particular, the Plaintiff herein.

42. Defendant, while regularly engaged in the business activities aforementioned, did design, develop, manufacture, produce, test, sell, market and/or distribute a certain drug product, more particularly known as Vioxx, which was ingested by Plaintiff.

43. At all times herein mentioned, the said drug product Vioxx was in a defective condition and unsafe and Defendant, individually, jointly and severally, knew or had reason to know that said product was defective and unsafe, especially when used as intended.

44. The said drug product Vioxx was inherently dangerous.

45. At the time of the occurrence and ingestion by Plaintiff, the said drug product, Vioxx, was being used for the purposes and a manner normally intended.

46. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and/or perceived their danger.

47. As a direct and proximate result of the defective condition of Vioxx, manufactured and supplied by Defendant, Plaintiff was caused to sustain severe

and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

48. By reason of the foregoing, the Defendant has become strictly liable in tort to the Plaintiffs.

49. By reason of the foregoing, Plaintiff has been damaged as against Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

SECOND CAUSE OF ACTION
(Negligence and Negligence per se)

50. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

51. The negligence of the Defendant, its agents, servants, and/or employees, included but was not limited to the following acts or omissions:

(a) manufacturing, producing, promoting, formulating, creating, and/or designing Vioxx without testing it for use in pregnancy;

(b) selling Vioxx without making proper and sufficient tests to determine the dangers and contra-indications thereof;

(c) negligently failing to adequately and correctly warn the public and the medical profession of the dangers and contra-indications and side effects inherent in the aforesaid drug and failing to provide adequate instructions regarding safety precautions to be

observed by users, handlers, and persons who would reasonably and foreseeably come into contact with said product;

(d) negligently advertising and recommending the use of the aforesaid drug without sufficient knowledge as to its dangerous propensities;

(e) negligently representing that the said drug was safe for use for its intended purpose, when, in fact, it was unsafe;

(f) not conducting sufficient testing programs to determine whether or not the aforesaid drug was safe for use; in that Defendants herein knew or should have known that said drug was unsafe and unfit for use by reason of the dangerous effects, contra-indications and dangers to the uses of Vioxx;

(g) misrepresenting the risks of Vioxx to the FDA; in knowing that it was a substance which caused underestimated injury to the Plaintiff herein, and all users of Vioxx, generally;

(h) improperly obtaining the approval of the FDA to market the drug, Vioxx, by alleging a favorable safety profile, when Defendants knew or should have known the cardiovascular risks associated with Vioxx;

(i) failing to adequately inform doctors who prescribed Vioxx of the serious side effects and/or risks associated with Vioxx; and

52. As a direct and proximate result of the aforementioned negligence on the part of the Defendant, Plaintiff was caused to sustain severe and grievous personal

injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

53. Based upon the foregoing, it is further alleged that Defendant's conduct, actions, and/or inactions amounted to and were in fact acts/actions of negligence per se, and Plaintiff sustained injuries and damages as set forth herein as a result of same by Defendant.

54. By reason of the foregoing, Plaintiff has been damaged as against Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

THIRD CAUSE OF ACTION
(Breach of Express Warranty)

55. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

56. Defendant, expressly represented to the users, including Plaintiff and/or her physicians that said drug Vioxx was safe and fit for use for the purposes intended, that it was of merchantable quality, and that it did not produce any side effects dangerous to life, and that it was adequately tested and fit for its intended use.

57. Members of the medical community relied upon the representations and warranties of the Defendant for use and ingestion of said drug Vioxx in prescribing, recommending and/or dispensing same.

58. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that said drug Vioxx was

not safe and fit for the use intended, and, in fact, produces serious injuries to the user and the offspring of the user.

59. As a result of the aforementioned breach of warranties by Defendant, Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

60. By reason of Defendant's actions as aforementioned, Defendant is liable to Plaintiffs.

61. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

FOURTH CAUSE OF ACTION
(Breach of Implied Warranty)

62. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

63. At all times herein mentioned, the Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, sold, purchased, prescribed, and/or administered the aforesaid Vioxx as described above and prior to the time that Plaintiff ingested said product.

64. The Defendant impliedly represented and warranted to the users and their physicians that the aforementioned drug product, more particularly known as Vioxx, was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

65. The said representations and warranties aforementioned were false, misleading, and inaccurate in that said drug product Vioxx, was unsafe, unreasonably dangerous, improper, not of merchantable quality, and/or defective.

66. Vioxx was injected into the stream of commerce by the Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

67. As a result of the aforementioned breach of warranties by Defendant, Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

68. By reason of Defendant's actions as aforementioned, Defendant is liable to Plaintiff.

69. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

FIFTH CAUSE OF ACTION
(Fraudulent Misrepresentation)

70. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

71. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, the FDA, and/or the public in general, that said product, Vioxx, had been tested and found to be safe and effective.

72. The representations made by Defendant were, in fact, false.

73. When said representations were made by Defendant, it knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

74. These representations were made by said Defendant with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and purchase said product, Vioxx, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

75. At the time the aforesaid representations were made by the Defendant and, at the time that the Plaintiff used the product, Vioxx, the Plaintiff, and/or her healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

76. In reliance upon said representations, the Plaintiff was induced to and did use the product, Vioxx, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of to sustain severe and permanent personal injuries in the future.

77. Said Defendant knew and was aware or should have known that Vioxx had not been sufficiently tested, was defective in nature, and that it lacked adequate warnings, at all times herein mentioned.

78. Defendant knew or should have known that its Vioxx had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous.

79. Defendant brought its product, Vioxx to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff herein.

80. As a result of the aforementioned fraudulent conduct by Defendant, Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

81. By reason of Defendant's actions as aforementioned, Defendant is liable to Plaintiffs.

82. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

SIXTH CAUSE OF ACTION
(Fraudulent Concealment)

83. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

84. At all times during the course of dealing between Defendant and Plaintiff, Defendant misrepresented that the product, Vioxx, was safe for its intended use.

85. Defendant knew or was reckless in not knowing that its

representations were false.

86. In representations to Plaintiff and/or her healthcare provider, Defendant fraudulently concealed and intentionally omitted the following material information:

(a) that Vioxx was not safe;

(b) that Defendant was aware of Vioxx's dangers;

(c) that Vioxx was defective, and that it caused dangerous side effects, including but not limited to heart attacks, strokes, and death, as well as other severe and permanent health consequences;

(d) that patients needed to be monitored more regularly than normal while using Vioxx;

(e) that Vioxx was manufactured negligently;

(f) that Vioxx was manufactured defectively;

(g) that Vioxx was manufactured improperly;

(h) that Vioxx was designed negligently;

(i) that Vioxx was designed defectively;

(j) that Vioxx was designed improperly;

(k) that Vioxx was inadequately tested, pre-market;

(l) that Vioxx was inadequately tested post-market;

(m) that safety testing of Vioxx was not disclosed to the public and/or healthcare authorities;

(n) that Vioxx was not subject to proper pre-market safety testing; and

(o) that Vioxx was not subject to proper post-market testing.

87. Defendant was under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the product, Vioxx.

88. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the product, Vioxx, including the Plaintiff, herein.

89. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of Vioxx was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or her physicians, hospitals and healthcare providers into reliance, continued use of Vioxx, and actions thereon, and to cause them to purchase Vioxx and/or to continue to use the product.

90. Defendant knew that Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding the product, Vioxx.

91. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on Defendant's concealment and/or omissions of fact.

92. As a result of the aforementioned fraudulent concealment by Defendant, Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

93. By reason of Defendant's actions as aforementioned, Defen-

dant is liable to Plaintiff.

94. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

SEVENTH CAUSE OF ACTION
(Negligent Misrepresentation)

95. Plaintiff repeats, reiterates and realleges each and every allegation contained in each of the foregoing paragraphs inclusive, with the same force and effect as if hereinafter set forth at length.

96. Defendant had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that said product, Vioxx, had been tested and found to be safe and effective.

97. The representations made by Defendant were, in fact, false.

98. Defendant failed to exercise ordinary care in the representation of the product, Vioxx, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented that Vioxx had a high risk of unreasonable, dangerous side effects.

99. Defendant breached their duty in representing the product, Vioxx's serious side effects to the medical and healthcare community, to the Plaintiff, and/or the FDA and the public in general.

100. As a result of the negligent misrepresentations of the Defendant set forth hereinabove, said Defendant knew and were aware or should

have known that the product, Vioxx had been insufficiently tested, that it had not been tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable, dangerous side effects for permanent and severe injury, including death.

101. As a result of the aforementioned negligent misrepresentation by Defendant, Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

102. By reason of Defendant's actions as aforementioned, Defendant is liable to Plaintiffs.

103. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

EIGHTH CAUSE OF ACTION
(Fraud and Deceit)

104. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

105. Defendant conducted research and used Vioxx as part of their research.

106. As a result of Defendant's research and testing, or lack

thereof, Defendant distributed blatantly and intentionally false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Vioxx was safe for use as a means of relieving arthritis and acute pain.

107. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

108. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff herein, as well as her respective healthcare providers and/or the FDA.

109. The information distributed to the public, the FDA, and the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

110. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Vioxx was safe for use to relieve arthritis and pain.

111. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included false representations that Vioxx was not injurious to the health and/or safety of its intended users.

112. These representations were all false and misleading.

113. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant's product, Vioxx, and results that demonstrated that the Vioxx was not safe, causing risks of heart attack and stroke.

114. Defendant intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Vioxx, specifically but not limited to Vioxx not having dangerous and serious health and/or safety concerns.

115. Defendant intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Vioxx, specifically but not limited to Vioxx being as safe a mean to relieve arthritis and other acute pain.

116. That it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, the Plaintiff, to falsely ensure the quality and fitness for use of Vioxx and induce the public, including but not limited to the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Vioxx.

117. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Plaintiff that Vioxx was fit and safe for use as pain reliever.

118. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals,

the FDA and the Plaintiff that Vioxx was fit and safe for use as pain relief medication.

119. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals and/or the Plaintiff that Vioxx did not present a health and/or safety risk.

120. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals and/or the Plaintiff that Vioxx did not present a health and/or safety risk.

121. That these representations and others made Defendant were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

122. That these representations and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff herein, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or their respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispenses, recommend, and/or prescribe Vioxx.

123. That Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Vioxx to the public at large, the Plaintiff, in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not safe.

124. That Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Vioxx by

concealing the suppressing material facts regarding the dangerous and serious health and/or safety concerns of Vioxx.

125. That Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Vioxx and/or that their respective healthcare providers would dispense, prescribe, and/or recommend same.

126. Defendant, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as their respective healthcare professionals would rely upon the information being disseminated.

127. Defendant utilized direct to consumer adverting to market, promote, and/or advertise Vioxx.

128. That at the time the representations were made, the Plaintiff and/or their respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Vioxx.

129. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant, nor could the Plaintiff with reasonable diligence have discovered the true facts.

130. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Vioxx, Plaintiff and/or

her healthcare providers would not have purchased, used and/or relied on Vioxx for pain relief.

131. That the Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

132. As a result of the Defendant's aforementioned conduct, which constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly, and/or purposefully on the Plaintiff, the Plaintiff was caused to sustain severe and grievous personal injuries, as set forth herein, and incurred past and will incur future medical expenses, lost wages (past and future), and all other damages available under the law.

133. By reason of Defendant's actions as aforementioned, Defendant is liable to Plaintiffs.

134. By reason of the foregoing, Plaintiff has been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.